REMARKS/ARGUMENTS

Reconsideration is respectfully requested.

This Response is responsive to the non-final Office action dated January 12, 2011, setting forth a shortened three-month statutory period for reply. A petition and fee for a two-month extension of time to reply accompany this Amendment and Response.

Claims 14-15, 18-20, 22-23, 32-34, 36-43, and 45-55 are pending in the application. Claims 14 and 22 are independent claims. By this Response, no claims are amended, no claims are added, and no claims are cancelled. Accordingly, after entry of this Response, claims 14-15, 18-20, 22-23, 32-34, 36-43, and 45-55 remain pending in the application, with claims 14 and 22 are independent claims.

Applicants have not publicly dedicated, or abandoned, any unclaimed subject matter. Further, the Applicants have not acquiesced to any rejections made by the Examiner in the Office action. Applicants reserve the right to pursue prosecution of any presently or previously excluded or cancelled claim embodiments in one or more future continuation and/or divisional applications.

I. Claim Rejections Under 35 U.S.C. § 112

Claims 32, 42, 45, 52, and 54 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Patent Office (the "Office") argues that the claims "contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." The Office argues that the limitations of the present claims "with or without about before the percentage" were not present in the application as filed. While the Office concedes that "concentrations in the specification may be combined to create new ranges," the rejected claims "recite data points that are new, that are not present in [the cited paragraphs], and that, as a result, may not be combined with other data points to create new ranges.

The Office ignores the requirements of the M.P.E.P. According to the M.P.E.P., "[t]o comply with the written description requirement of 35 U.S.C. 112, para. 1, . . . each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure." §2163.05. Thus, where range limitations are amended, "the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the

original disclosure." *Id.* The U.S. Court of Customs and Patent Appeals has found that express disclosure of a range teaches a claimed sub-range encompassed by the first range. *Application of Blaser*, 556 F.2d 534 (CCPA, 1977). Specifically, in *Blaser*, the court found a "disclosure of 60° C to 200° C . . . would likewise teach 80° C to 200° C as part of appellants' invention." *Id.* at 538 (citing approvingly to *In re Wertheim*, 541 F.2d 257 (CCPA 1976)). The Federal Circuit agrees, stating "[i]f lack of literal support alone were enough to support a rejection under § 112, then the statement . . . that 'the invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112,' is empty verbiage. *Union Oil Co. of Calif. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed.Cir.2000), quoting *In re Wertheim*, 541 F.2d. at 265. Compliance with § 112 paragraph 1 "ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims." *Id.* citing to *Vas-Cath, Inc. v Mahurkar*, 935 F.2d at 1555 (Fed.Cir.1991).

The Office is requiring *ipsis verbis* support, as expressly rejected by the M.P.E.P. and the courts. The instant Specification, at paragraph [017], states that CoQ10 may be solubilized in monoterpenes "in concentrations up to about 60% (weight to weight)." The Specification, at paragraph [018], further discloses that CoQ10 may be solubilized in ranges "from about 0.1 percent by weight to about 45 percent by weight," "from about 5 to about 50 percent," "from about 15 to about 40 percent w/w," and "from about 20 to about 35 percent w/w." Thus, one of skill in the art would recognize from the disclosure that Applicants were in possession of coenzyme Q-10 solubilized in limonene in concentrations from 0 or about 0.1 percent up to about 60 percent (weight to weight), as well as all sub-ranges therein.

The Office's rejection is at odds with the requirements of the M.P.E.P. and supporting court rulings.

Because the presently claimed concentrations of CoQ10 in limonene of "about 30 to about 45 percent by weight" (claims 32 and 42), "about 25 to about 50 percent by weight" (claim 45), and "about 30 percent to about 60 percent by weight" are within the scope of the subject matter disclosed in the Specification as filed, the Examiner's rejection is inapposite and should be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 103

The Office has maintained rejections to claims 14, 15, 18, 20, 22, 23, 32-34, 36, 42, 43, 45 and 46 remain rejected, and presently rejects claims 52-55 under 35 U.S.C. § 103(a) as

obvious over EP0888774 to Soft Gel (hereinafter "Soft Gel") in view of US 2003/0232095 to Garti et al. (hereinafter "Garti"), US 2004/0047922 to Elstner (hereinafter "Elstner"), and RITO Partnership document ("RITO"). Specifically, the Office argues that "Soft Gel teaches a solution of coQ10 in two carriers that are oils [rice bran oil and Vitamin E]." The Office concedes that "Soft Gel does not disclose dissolving the co Q in d-limonene," but argues that "Garti et al. disclose compositions, nano-scale emulsions, comprising co Q10 dissolved in d-limonene." The Office further argues that "Elstner discloses a nutraceutical composition comprising co Q10 dissolved in a mixture of γ-terpinene" and states that γ-terpinene is "an isomer of d-limonene derived from lemon oil, limonene being derived from orange oil." Finally, the Office argues that "[i]t is obvious to dissolve a compound in a solvent in which it is known to be soluble."

The concentration ranges recited in claims 14, 18, 22, 32-34, 42, 43, 45, 46, and 52-55 are also rejected by the Office. While the Office concedes that "Garti et al. do not disclose the solubility limit of co Q10 in d-limonene, . . . [Garti does] disclose, however, that, in the concentrated form of their composition, the oil phase contains 2.45% co Q10 and 17.22% d-limonene, as percentages of the whole." Regarding the presently claimed ranges, the Office argues that "the ranges recited in the claims do not appear to be associated with any particular result or effect," and therefore "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to dissolve as much co Q10 as possible in the d-limonene."

The cited references do not teach the presently claimed "coenzyme Q-10 solubilized in limonene to form a solution . . . with the proviso that the coenzyme Q-10 solubilized in limonene is not in an emulsion, suspension, or elixir," nor do they teach the presently claimed solution of coenzyme Q10 in limonene at "about 15 percent up to about 60 percent."

1. The Board of Patent Appeals and Interferences has stated that there is no reasonable expectation of success in combining limonene and CoQ10, according to the cited references, without the use of an emulsion.

According to the Board of Patent Appeals and Interferences (the "BPAI"), Garti teaches "the use of emulsions of limonene with enzyme CoQ10," and further that "Garti does not teach that any single solvent will result in solubilization of the CoQ10, but rather that it is the combination of specific components into an emulsion which permits the solubilization." *Ex parte* Michael Fantuzzi, Appeal 2010-012375 (the "BPAI Decision"), pp. 6-7. For these reasons, the BPAI, at page 7, stated that "there is no reasonable expectation of success in combining

limonene, coQ10, and other components and expecting that they will not form an emulsion but will continue to solubilize the coQ10."

Because Garti, Soft Gel, Elstner, and RITO do not provide one of skill in the art with a reasonable expectation of success in combining limonene and CoQ10 without the use of an emulsion, the Office's objection is inapposite and should be withdrawn.

2. The cited art teaches away from using solutions of coenzyme Q-10 in limonene to form a solution, "wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight," as currently claimed.

According to the M.P.E.P. "[a] prima facie case of obviousness may . . be rebutted by showing that the art, in any material respect, teaches away from the claimed invention." § 2144.05(III).

According to the BPAI, "Garti directly rebuts the underlying logic" the Office uses to reject the present claims as obvious. Specifically the BPAI Decision cited the statement by Garti "that the 'capability of these nano-sized self-assembled structured concentrates to solubilize the desired active component exceeds many-fold the solubility capacities of the aqueous or oil phase alone or of the aqueous or oil phase in the presence of an appropriate surfactant'." Thus, the BPAI found that "Garti does not teach that any single solvent will result in solubilization of the CoQ10, but rather that it is the combination of specific components into an emulsion which permits the solubilization." *BPAI Decision* at p. 7.

Applicants have previously argued that the cited art discloses that coenzyme Q10 is generally insoluble in oils and that the maximal solubility in a single compound is many fold lower than the presently claimed range. Garti teaches that even minimal solubility of coenzyme Q10 (2.45%) requires the use of a multi-component emulsion, which traps the insoluble coenzyme Q10. Specifically, Garti is directed to delivery methods for "[l]ipophilic compounds [that] are non-soluble in aqueous systems and frequently also in food grade organic solvents such as vegetable oils or alcohols." Garti, para. [0030]. Garti identifies coenzyme Q10 as one such lipophilic nutraceutical. Id. Garti solves the insolubility problem by avoiding the use of a single solubilizing compound. Even so, Garti's most concentrated coenzyme Q10 emulsion is only 2.45%. Example C:1 Micellar concentrate, para. [0040].

Garti is explicit in requiring the use of a multi-component emulsion to achieve the 2.45% coenzyme Q10 composition. More importantly, Garti teaches that the 2.45% coenzyme Q10 composition is far better than what can be expected with limonene, or any oil, alone. Garti states that "[t]he capability of . . . nano-sized self-assembled structured concentrates to

solubilize the desired active component exceeds many-fold the solubility capacities of the aqueous or oil phase alone or of the aqueous or oil phase in the presence of an appropriate surfactant." *Garti*, para. [0029]. Thus, Garti materially and explicitly teaches away from a solution of coenzyme Q10 and limonene "wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight."

EP0888774, RITO, and Elstner can not compensate for the failings of Garti. Neither Soft Gel, nor RITO teach or even mention limonene. While Elstner claims a preparation "contain[ing] a terpinene-containing etherial oil or terpinene," and coenzyme Q (Q10), there is simply no teaching of coenzyme Q-10 solubilized in limonene "to form a solution" as required in claims 14 and 22.

Because the teachings of Garti would discourage one of skill in the art from combining limonene and coenzyme Q10 to form a solution, the Office's rejection is inapposite and should be withdrawn.

3. The cited art does not disclose the presently claimed solution of coenzyme Q10 in limonene at "about 15 percent up to about 60 percent coenzyme Q-10 by weight."

According to the M.P.E.P, in order to support a rejection based on obviousness of numerical ranges: (1) the claimed ranges "overlap or lie inside ranges disclosed by the prior art," *In re Wertheim*, 541. F.2d 257 (CCPA 1976), (2) a reference "discloses a range encompassing a somewhat narrower claimed range," *In re Peterson*, 315 F.3d 1325 (Fed.Cir. 2003), or (3) a range is "disclosed in multiple prior art references instead of in a single prior art reference," *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317 (Fed.Cir. 2004). § 2144.05(I).

The Office has rejected dependent claims reciting percentages of coenzyme Q10 in limonene. *Office Action*, p. 4. However, the Office concedes that "Garti et al. do not disclose the solubility limit of CoQ10 in d-limonene," and that Garti only discloses a composition wherein "the oil phase contains 2.45% co Q10 and 17.22% d-limonene, as percentages of the whole." *Office Action*, p. 4. The Office argues that this combination "of co Q10 to d-limonene by weight is 2.45:17.22, which is a ratio of about 14:100."

As described above, Garti is explicit in directing those of skill in the art away from the present claims. Further, Garti argues that 2.45% coenzyme Q10 composition, which is achieved only through use of the multi-component emulsion, is far better than what could be expected with limonene alone: "[t]he capability of . . . nano-sized self-assembled structured concentrates to solubilize the desired active component exceeds many-fold the solubility capacities of the aqueous or oil phase alone or of the aqueous or oil phase in the presence of an appropriate surfactant." *Garti,* para [0029]. Thus, not only is there no overlap of the presently claimed

range with the range of Garti's emulsions, but Garti teaches that the highest percent coenzyme Q10 that maybe achieved by a single solvent is several fold lower than 2.45%. *Garti*, para [0029] (stating that "[t]he capability of these nano-sized self-assembled structured concentrates to solubilize the desired active component exceeds many-fold the solubility capacities of the aqueous or oil phase alone or of the aqueous or oil phase in the presence of an appropriate surfactant.").

EP0888774, RITO, and Elstner can not compensate for the failings of Garti. Neither Soft Gel, nor RITO teach or even mention limonene. While Elstner claims a preparation "contain[ing] a terpinene-containing etherial oil or terpinene," and coenzyme Q (Q10), there is simply no teaching of coenzyme Q-10 solubilized in limonene "to form a solution, wherein said solution is about 15 percent up to about 60 percent," or wherein the solution is not an emulsion as required in claims 14 and 22.

Because the cited art does not teach the presently claimed ranges of solubilized CoQ10 and limonene, the Office's rejection is inapposite and should be withdrawn.

4. The presently claimed ranges are not the result of "routine optimization" because the cited art does not recognize that coenzyme Q10 may be solubilized in limonene "to form a solution."

According to the M.P.E.P., even where disclosed ranges do not overlap, it may be obvious to optimize conditions, including a concentration range. M.P.E.P. § 2144.05(II). For example, "[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," because it is "[t]he normal desire of scientists or artisans to improve upon what is already generally known." *Id.* citing to *In re Aller*, 220, F.2d 454 (CCPA 1955) and *In re Peterson*, 315 F.3d at 1330.

Before optimization may be found to be obvious, the M.P.E.P. requires that the optimized "parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *Id.* citing *In re Antonie*, 559 F.2d 618 (CCPA 1977).

In its rejection of claims reciting percentages of coenzyme Q10 in limonene, the Office concedes that "Garti et al. do not disclose the solubility limit of CoQ10 in d-limonene," but argued that "it would have been obvious to one of ordinary skill in the art at the time of the invention to dissolve as much co Q10 as possible in the d-limonene and in the solvent mixture of limonene." In supporting this argument the Office contends that "[t]he solubility limit of

CoQ10 in any solvent or solvent mixture would have been readily determined by the artisan of ordinary skill, such a determination being routine in the art." *Id.*

Simply put, the solubility limit of CoQ10 would not have been readily determined by the reasonably skilled artisan, because Garti teaches that solubility limit of coenzyme Q10 in any oil alone is many fold lower than 2.45%. *Garti*, para. [0029]. As described above, Garti teaches that a multi-component emulsion must be used to obtain even a 2.45% coenzyme Q10 composition. Thus, according to Garti, it certainly is not within the realm of "routine optimization" to arrive at a percent concentration of between about 15% and about 60%, as presently claimed, where that claimed range is several fold higher than concentration taught by Garti (2.45%).

EP0888774, RITO, and Elstner can not compensate for the failings of Garti. Neither Soft Gel, nor RITO teach or even mention limonene. Again, while Elstner claims a preparation "contain[ing] a terpinene-containing etherial oil or terpinene," and coenzyme Q (Q10), there is simply no teaching of coenzyme Q-10 solubilized in limonene "to form a solution" as required in claims 14 and 22.

5. Because independent claims 14 and 22 are non-obvious in light of the cited art, all claims depending therefrom are also non-obvious.

The M.P.E.P. states that "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." § 2143.03 *citing, In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

As detailed above, claims directed to a solution of coenzyme Q10 in limonene, "wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight" are not obvious in light of the cited art. Thus, because claims 14 and 22 are non-obvious, all other claims that depend from these independent claims are also non-obvious.

CONCLUSION

After entry of the above listing of claims and remarks 14-15, 18-20, 22-23, 32-34, 36-43, and 45-55 are pending in the application. In accordance with the amendments and arguments set forth herein, the Applicants respectfully submit the application and all claims are in a condition for allowance, and request such prompt allowance.

This Response is in reply to the Office Action mailed January 12, 2011, setting a response time of three months, with extensions available to July 12, 2011. Since June 12, 2011 was a Sunday, the two-month extension date for response to the Office Action is Monday, June 13, 2011. See 37 C.F.R. § 1.7.

This Response is filed with a petition for a two-month extension of time and a request to charge Deposit Account No. 04-1415 for the extension of time fee in the amount of $245. The Applicants believe no further fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this as authorization therefor and please charge such fees to Deposit Account number 04-1415.

Should any issues remain that the Examiner believes may be dealt with in a telephone conference, she is invited to contact the undersigned at 303-629-3400.

Dated this 13th day of June, 2011.

Respectfully submitted,

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